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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,899	03/31/2004	John Riley Hawkins	101896-662 (DEP5055USNP)	1803
21125 7590 09/05/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
GANESAN, SUBA				
ART UNIT		PAPER NUMBER		
3774				
NOTIFICATION DATE		DELIVERY MODE		
09/05/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

### Office Action Summary

**Application No.**

10/813,899

**Applicant(s)**

HAWKINS ET AL.

**Examiner**

SUBA GANESAN

**Art Unit**

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-10, 12, 13 and 54-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 9, 10, 12, 13, 54-61 and 63-66 is/are rejected.
- 7) ☒ Claim(s) 8, 62 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 66 is objected to because of the following informalities: Claim 66 is the same as claim 13. Since both claim 66 and claim 13 depend from claim 12, the claim is redundant. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 6-7, 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (U.S. Pat. No.: 6,224,607).

4. Michelson discloses an anterior method (col. 9 line 25) for implanting an artificial disc (implants, for example fig. 29) comprising:

(a) fixing a position of a midline marker 100 and 118 such that a portion of the midline marker embeds in the face of a vertebral body (shoulder 108) to mark a midline thereof (using reference marks 118),

(b) inserting a distraction instrument (fig. 5) into the intervertebral space using the midline marker as a guide (via reference marks 118)

(c) selecting an artificial disc for implantation (fig. 29, for example); and

(d) inserting the artificial disc using the midline marker as a guide (fig. 29, for example).

The implant is considered to be an artificial disc because it replaces the native disc. A window is removed from the annulus (see fig. 27-29). The disc is fitted with trial spacers 291 (see fig. 30 and related description of spacer 291). It is considered inherent that the nucleus pulposus would be removed to create such a space. The endplates are shaped via a bone compactor 240, which is guided by the midline marker (via reference marks 118) and includes shaping blades 244.

***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 3-4, 56-61, and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (U.S. Pat. No.: 6,224,607).
7. Michelson is explained supra. Michelson discloses a radiopaque pin 104 used to verify the disc space. However, this pin is located on the midline marker instrument 100. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have included the pin on a verification instrument separate from the midline marker, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177,179.
8. Michelson further discloses a shoulder 108 of a midline marker 100 which abuts the anterior aspect of adjacent vertebral bodies. However, Michelson lacks a midline marker which embeds in the face of only a single vertebral body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have

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modified the implantation methods of Michelson such that the midline marker embeds in the face of only a single vertebral body (using shoulder 108) for the purpose of providing a lower profile marker such that visualization of the spine is permitted during use of the midline marker.

9. Claims 12-13, 54-55, and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (U.S. Pat. No.: 6,224,607) in view of Nolan (U.S. Pat. No.: 6,117,174).

10. Michelson is explained supra. However, Michelson lacks implanting an artificial disc with endplates, a core and a retention clip. Nolan teaches the use of an implant 10 with endplates 18, 20, a core 14 and a retention clip C resulting in a prosthesis that is easier to install and has improved integrity. It would have been obvious to one of ordinary skill in the art to have modified the methods of Michelson to include the implant of Nolan for the purpose of providing an implant that is easier to install and has better implant integrity.

#### ***Allowable Subject Matter***

11. Claims 8 and 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

12. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection. This action has been made non-final in view of the new rejections.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./  
Examiner, Art Unit 3774  
/William H. Matthews/  
Primary Examiner, Art Unit 3774